# 6 LABELING AND ATTRIBUTES



Required and recommended labeling for medical gloves are described below along with examples of typical labeling for dispenser boxes of examination gloves and typical labeling for a unit package containing a pair of surgeon's gloves.

## BASIC LABELING REQUIREMENTS (21 CFR Part 801)

### Name and Place of Business (21 CFR 801.1)

- The label of a glove shall contain the name and place of business of the manufacturer, packer, or distributor including the street, address, city, state, and zip code.If the street address of the identified manufacturer, packer or distributor is in the local (domestic) telephone directory, the street address can be omitted.
- If the listed firm is not the manufacturer, then the listed firm's name must be qualified by an appropriate statement such as, "Manufactured for..." or "Distributed by...."

**Statement of Identity (21 CFR 801.61)**

- The statement of identity of the glove must be listed on the principal display panel. If the glove is made of synthetic polymers, the statement of identity should include the common, generic or scientific name of the polymer of which the glove is composed. "Synthetic" used alone does not fully characterize the composition of the glove and may mislead the purchaser.
- The identity statement must list the common name of the device such as powdered latex surgeon's gloves, powdered latex patient examination gloves, powder-free latex surgeon's gloves, powder-free latex patient examination gloves, latex finger cots, powdered nitrile examination gloves, powder-free vinyl examination gloves, etc.
- The identity statement must be in bold type, reasonably related in size to the most prominent printed matter on the display panel, and must be in lines generally parallel to the base of the package when rested.
- All labeling shall be in English with the exception of those products distributed solely within Puerto Rico or a United States (U.S.) Territory where the predominant language is not English. If any representation on the device label or labeling appears in a foreign language, then all required labeling shall also appear in that foreign language.

**Net Quantity of Contents Statement (21 CFR 801.62)**

The label must contain a statement of net quantity of contents in terms of weight, numerical count, or statements of both numerical count and weight. Whichever statement of net quantity of contents is used, it must be clearly and understandably stated on the label; for example, "100 gloves -- packaged by weight."

The declaration shall appear as a separate item in the lower 30 percent of each principal display panel; and be separated by at least a space equal to the height of the lettering used in the declaration, from other information appearing above and below, and separated by at least twice the width of the letter "N" from labeling to the left or right.

**Country of Origin**

The label must contain the country of origin if other than the U.S. This is a U.S. Customs requirement.

**Adequate Directions for Use (21 CFR 801.5)**

Disposable medical gloves should be labeled "single use only," if a symbol is used. The label for **surgeon's** gloves must contain any necessary directions for use. The following statement is required (36 FR 9475, May 25, 1971) for sterile **powdered** surgeon's gloves:

**"Caution:** After donning, remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method."

A similar caution is recommended for **powdered patient examination** gloves because patient examination gloves are used in a variety of circumstances, including procedures where the surface of the glove contacts wounds, body cavities, or other possible routes of contamination. If conditions warrant, the user may wish to remove residual powder from the gloves prior to use in order to minimize the potential for adverse effects. For this reason, FDA recommends the following statement appear on each box of powdered patient examination gloves.

"**Caution:** Users should consider the circumstances of use in deciding whether to remove powder from gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method."

**Powder and Protein Labeling (Proposed 21 CFR 801.440)**

The labeling of gloves would be required to bear identifying statements per proposed 21 CFR §801.440 *User labeling for powdered and powder-free surgeon's and patient examination gloves.* Powder and protein levels shall be displayed in accordance with the labeling requirements as defined in the special control, *Medical Glove Guidance Manual* (this manual).

Manufacturers with cleared submissions under section 510(k) of the act for surgeon's or patient examination gloves are **not** required to submit new 510(k) submissions for labeling changes to add protein and/or powder levels. However, the manufacturer must keep appropriate records documenting the labeling changes.

The caution statements proposed in §801.440 would be required to appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging, the outside package, container or wrapper, and the immediate device package, container, or wrapper. These statements shall be prominently displayed in bold print in conformance with section 502(c) of the act.

**Natural rubber latex powdered gloves.** For natural rubber **latex powdered** surgeon's gloves and powdered patient examination gloves, the statement required in 21 CFR §801.437(d) would be superseded by 21 CFR §801.440(a) to read as follows:

**"Caution: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain not more than 120 mg powder and 1200 µg extractable protein per glove. This product contains no more than [insert level] mg powder and no more than [insert level] µg extractable protein."**

**Synthetic material powdered gloves.** For **synthetic material** powdered surgeon's or powdered patient examination gloves, the labeling would be required by §801.437(b) to prominently bear the following statement:

**"Caution: Glove powder is associated with adverse reactions. FDA recommends that this product contain no more than 120 mg powder per glove. This product contains no more than [insert level] mg powder per glove."**

Note that §801.440 would not require additional labeling for **powder-free** synthetic material gloves.

**Natural rubber latex powder-free gloves.** For natural rubber **latex powder-free** surgeon's gloves and powder-free patient examination gloves, the statement required in §801.437(d) of this subchapter would be superseded by §801.440(c) to read as follows:

**"Caution: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain no more than 1200 µg extractable protein per glove. This product contains [insert level] µg extractable protein per glove."**

At present, the FDA does not allow a protein labeling statement or claim below the current 50µg/gram of glove sensitivity limit of the ASTM Lowry test method (note that for a 6 gram glove, 50µg/gm translates to 6 x 50 = 300µg per **glove**). This lower limit for protein labeling may change if the ongoing work on ASTM D 5712 results in a more sensitive test method.

For gloves to be labeled as containing 50µg/gram or less per glove of extractable protein, the labeling should also state:

**"Caution: Safe use of these gloves by latex sensitized individuals has not been established."**

**Expiration Date [Proposed 21 CFR 801.440(d)]**

Since the early 1990s, the FDA has encouraged manufacturers to collect data to substantiate the shelf life (expiration date) of each glove product they manufactured. Proposed 21 CFR §801.440(d) would require that all surgeon's and patient examination gloves bear an **expiration** date as reprinted below:

(d) All surgeon's and patient examination gloves shall bear an expiration date as follows:

(1) The expiration date shall state the month and year of the shelf life as supported by data from the studies described in paragraph (d)(3) of this section;
(2) The expiration date must be prominently displayed on the exterior of the primary and retail package, and on the shipping carton;
(3) The expiration date must be supported by stability studies demonstrating acceptable physical and mechanical integrity of the product over the shelf-life of the product from its date of manufacture;
(4) For each glove design, the testing data and stability study protocol supporting an expiration date must be maintained by the manufacturer for a period equivalent to the design and expected life of that glove type, and shall be made available for inspection and copying by FDA; and
(5) Sterile surgeon's and patient examination gloves that have a date of expiration based on sterility that is different from the expiration date based upon physical and mechanical integrity testing shall bear only the earlier expiration date.

The expiration date should reflect the month and year, for example: January 2002. It should **not** be stated as 1/10/02 because this could or would be interpreted as October 1, 2002 in some parts of the world, resulting in the use of outdated and degraded gloves.

In the past, expiration dates were based on real time studies by manufacturers. FDA has drafted guidance that allows manufacturers to make a shelf life claim based on accelerated aging techniques and it will be placed on the CDRH web site. Such claims must be verified by real time studies.

Aging studies are performed with a statistically valid number of representative gloves under specified conditions according to a written protocol. If you plan to have a shelf life of several years, you should consider protecting the dispenser box from moisture and contamination. Your packaging system is important for maximizing the shelf life of your products. Increasing shelf life may require dispenser boxes to be laminated or shrink wrapped with plastic film or other method to reduce exposure to moisture and ozone.

Manufacturers with cleared submissions under section 510(k) of the act for surgeon's or patient examination gloves are **not** required to submit new 510(k) submissions to add an expiration date to the labeling.

## ADDITIONAL LABELING

### Lot Number

It is customary for the package of medical gloves to bear a lot number. A lot number should identify the batch of compounded latex, the production lines, the production shift, and, if sterile, the sterilization run. A lot number is required by ASTM standards D 3577 section 10.2, D 3578 section 9.3 or D 5250 section 9.3. The lot number should be visible -- **not** placed on the inside of a dispenser box.

### Donning Powder or Lubricant Identification

If surgeon's gloves are powdered, they must be powdered with an absorbable dusting powder which has received FDA **approval** under either an NDA or a PMA, and the labeling should inform users with a statement such as, **"Powdered with absorbable dusting powder."**

If patient examination gloves are powdered, the powder should meet the United States Pharmacopoeia (U.S.P.) monograph for absorbable dusting powder or be shown to be equivalent in terms of safety and effectiveness. The 510(k) for the gloves must state the type, specifications and source of powder or other donning lubricant used on the gloves. This data must demonstrate the biocompatibility of the powder and its lack of adverse effects upon the physical characteristics of the glove. U.S.P powder is commonly used on examination gloves so the corresponding labeling statement should read, **"Powdered with absorbable dusting powder, U.S.P."**

### Standards

FDA does not object to manufacturers stating in their labeling that their product meets a spe-

cific national or international consensus standard(s). The labeling should clearly identify the standard by name or alphanumeric text including the year published or other information needed to identify the specific standard. Labeling shall not be confusing or misleading; therefore, FDA expects the product to meet all of the applicable parts or parameters of the standard, if such a claim is made. This is guidance for a labeling claim and thus is different from a premarket submission which may contain a declaration of conformity with any or all parts of a standard without an associated claim in the labeling.]

If the label states that a product meets a specific standard, the product delivered to the customer must meet the standard. Thus, the manufacturer should have design, expiration and/or other valid shelf life data on file to support their claim.

**Bar Coding**

Bar coding is favored in several countries such as Europe, Japan and the United States for quick tracking of distributor or hospital inventory. While not an FDA requirement, purchasers may demand that products they buy contain a bar code on cartons and dispenser boxes. Many manufacturers have started placing bar codes on cartons and on the bottom of dispenser boxes.

**National Health Related Items Code**

The National Health Related Items Code (NHRIC) is a voluntary identification numbering system for medical devices. Purchasers may request that you provide an NHRIC number on your medical devices. The NHRIC is assigned and administered by the CDRH Office of Compliance. The phone number is 301-827-4555 ext.104. If you choose to place an NHRIC on your labeling, it should be preceded by the letter "H" to distinguish it from NDC or Universal Product Code (UPC) numbers and it should prominently appear in the top third of the principal display panel.

**ATTRIBUTE LABELING**

In addition to basic labeling described above, manufacturers may have labeling claims for the attributes of their gloves. The claims should be for characteristics of their gloves that are substantially equivalent to characteristics of predicate gloves or that meet a consensus standard. Some attributes are color, flavor, scent, and thickness. Data must be submitted in a premarket notification to support all claims. Ambiguous labeling claims such as "extra thick" or "super-sensitive" should not be included. However, a factual and definitive statement such as, "Twice the minimum ASTM thickness." is acceptable. Claims may not be false or misleading in any way, nor may the quality of the product fall below that which it purports or is represented to possess.

**"Powder-Free"**

Gloves with trace amounts of residual former-release and donning powders are commonly referred to as "powder free." Most manufacturers dip the glove mold, commonly referred to as a "former," into a solution of calcium carbonate and calcium nitrate. After controlled drying, the coated former is dipped into the latex solution and a glove is created on the former. The calcium carbonate (powder) helps release the glove from the former. Only a small amount of calcium carbonate remains on the "uncured" glove and most of it is removed by leaching and washing.

The finished gloves are tacky and will stick to the hand; therefore, a lubricant is usually applied to the inner side of the gloves to aid in donning. Some manufacturers use surface chlorination and washing to remove manufacturing former-release or stripping powder and to give the glove a slick texture which precludes the need for donning powder. Other manufacturers remove the former-release or stripping powder from the surface of the gloves and use a non-powder donning lubricant such as silicone. Various manufacturers also use proprietary methods to achieve powder-free gloves.

FDA requires a 510(k) for a powder-free glove or a change from a powdered to a powder-free glove. The manufacturing process for producing a powder free glove should be described in detail in the premarket notification. Information demonstrating that the process used does not have a significant effect on the finished glove specifications should also be included.

ASTM has published a standard method D 6124 for collecting and measuring the manufacturing debris, **residual** former-release powder, etc., on a powder-free glove.

To establish a "powder-free" claim, FDA recommends no more than 2 mg of residual or trace powder and debris per glove, as determined by the ASTM D 6124 test method or an equivalent method. In order for an applicant to substantiate a "powder-free" claim in their 510(k) submission, the applicant should state whether the manufacturing process for the glove includes **any** powder such as a former-release powder and/or a donning powder. If it does, the applicant should provide:

1. a description of the powder(s) introduced at any stage of the glove manufacturing process such as former release or stripping powder and donning powder;

2. a detailed description of the process to remove the added powder(s);

3. a description of the release specification supporting the powder-free claim and a brief summary of the final product testing to ensure the gloves meets this specification;

4. a description of how the glove is designed or manufactured to compensate for the lack of donning powder, or reasons why the compensation is not necessary, including a full characterization such as the chemical identity, specifications, and biocompatibility of any material such as silicone added to the glove to facilitate glove donning; and

5. a certification that the finished powder-free glove meet ASTM standard D 3577, D 3578 or D 5250 or equivalent recognized standard, as appropriate.

If the **entire** manufacturing process does **not** include any former release on donning powder, then the applicant need only discuss items 4 and 5 in the above list.

**Protein Label Claims**

Latex protein is reported as a cause of Type I sensitivity in some individuals who have been exposed to latex containing devices. Repeated exposure to latex protein is believed to increase the probability that an individual will become sensitized. Since May 1991, the FDA has recommended

that manufacturers of latex devices reduce the water-extractable protein on their natural rubber latex devices. Such reduction is required by the Quality System Regulation, 21 Code of Federal Regulations, Part 820 by 820.3(p), Manufacturing Material, and 820.70(h), Manufacturing Material. However, in 1991 a labeling claim was not allowed in a 510(k) submission for a "protein content labeling claim" because a standard test method for measuring water-extractable protein in natural rubber latex did not exist. Subsequently, the American Society for Testing and Materials, published the ASTM *Standard Test Method for Analysis of Protein in Natural Rubber and its Products, D 5712-95*. Afterwards, 510(k) submissions with protein claims were accepted by CDRH.

As noted above, FDA would require in proposed 21 CFR 801.440 that the labeling for all latex medical gloves bear a statement declaring the maximum water soluble protein level per glove as measured by the current ASTM D 5712 modified Lowry method or an equivalent method. The FDA recommended limit for water extractable protein is 1200 µg per **glove**.

Please note that the FDA does not allow a labeling claim for extractable protein below 300µg per **glove** because of current limits to the sensitivity of the ASTM D 5712-95 Lowry test method which is 50 µg per gram of glove. For a 6 gram glove, 50 µg per **gram** of glove translates to 300µg per **glove** ( 6 grams X 50 µg/gm = 300 µg). This lower labeling limit may change if the ongoing work on ASTM D 5712 results in a more sensitive test method.

The water-extractable protein should be measured on recently manufactured finished gloves that have undergone accelerated aging per ASTM standard D 3577 or D 3578 or real time aging. For the data submitted in your 510(k), we suggest that accelerated aging be done for 7 days at 70° Centigrade or real time aging for 3 months to a year.

The statement declaring the maximum water soluble protein level should be based upon the **upper** process limit for each glove type as determined by testing. In the example shown graphically below, the upper process limit is 600µg water extractable protein per glove as determined by testing. Therefore, that lot of gloves should be labeled:

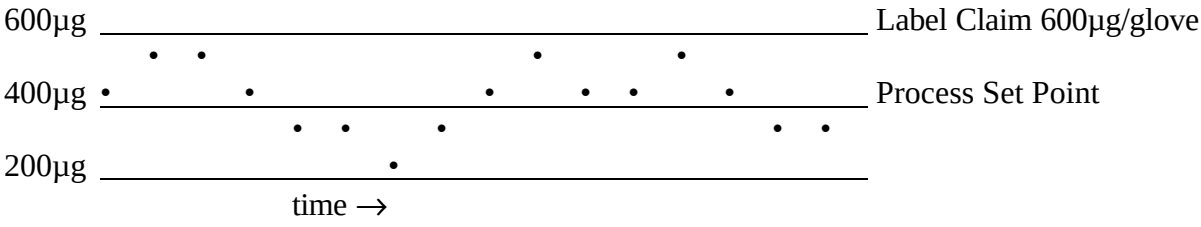
"This latex glove contains no more than 600µg extractable protein per glove."

Do **not** label the lot with either the process set point or the average level.

This is only an example. Your label statement should reflect actual values from your manufacturing lines. The levels shown in this example are not FDA limits, requirements or recommendations.

Note that the same principle should be applied to powder levels.

For this example, your manufacturing process set point or center operating point should be significantly less than 600µg per glove such that the set point **plus** process variations produce gloves that contain no more than 600µg per glove of water-extractable protein as shown in the following chart.




For this example, a portion of the labeling statement required by proposed 21 CFR §801.440 would be made as follows:

"This latex glove contains no more than 600µg extractable protein per glove."

To meet Quality System requirements, the processes used to control water-soluble proteins and manufacturing materials must be developed, validated, documented and, thereafter controlled. Validation is required because the protein and residual chemicals on each glove are not measured.

The labeling changes to dispenser boxes and any changes to manufacturing processes must be done according to Quality Systems change control requirements in §§820.30, 820.40 and 820.70. (However, examination gloves are not required to meet §820.30 until the effective date of the final rule when the reclassification to Class II becomes effective.

**Polymer-Coated Gloves**

If a manufacturer coats their gloves to bind extractable proteins and/or aid in donning, then the manufacturer should perform accelerated or real-time aging tests to show that the coating is effective for the normal expected life of the gloves. FDA is aware of complaints that coatings

have flaked off or delaminated before the gloves are used. On occasion, synthetic polymer gloves have been reported to be contaminated with latex proteins. Synthetic polymer gloves, polymer-coated latex gloves and any gloves with a specified protein level should not be exposed to air-borne protein-coated starch or dipped in any tank where regular protein containing latex gloves have been processed unless the tanks are thoroughly cleaned before the production of the specified protein or non-protein gloves.

**Chemical Sensitization**

As noted in the *Federal Register* final rule of September 30, 1997 "Latex-Containing Devices; User Labeling," FDA has developed guidance on chemical sensitization. Please refer to the document entitled, *"Draft Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Testing for Skin Sensitization to Chemicals in Latex Products,"* available on the World Wide Web at: http://www.fda.gov/cdrh/ode/944.html.

**Color and Flavor Additives**

Color or flavor additives added to medical gloves during the manufacturing process require biocompatibility data in the premarket notification submission. **The addition of colorants, other than traditional whiteners such as titanium dioxide, or the addition of a flavor to a medical glove is considered to be a significant change which requires a premarket notification submission [510(k)].** (Please see Chapter 5, *Biocompatibility*.)

Medical device labeling requirements do not require on the glove box or carton an "ingredients statement" listing the flavor agents or colorants used in the manufacture of the gloves.

**Chemotherapy Label Claim**

Chemotherapy gloves are specialty medical examination gloves and require premarket notification [510(k)] clearance from FDA before marketing. Chemotherapy gloves should meet the ASTM standard D 3578 or an equivalent standard for examination gloves; however, they are usually 0.10 mm or more in thickness which is more than the 0.08 mm minimum allowed for examination gloves.

To help assure that the 510(k) application is complete and to help FDA determine that the applicant's gloves are substantially equivalent to legally marketed chemotherapy gloves, the applicant may use the 510(k) format in Chapter 8 for examination gloves. Labeling, donning powder or lubricant, protein, powder-free, etc., requirements for chemotherapy gloves are the same as for examination gloves. In addition, the applicant should specify the chemicals against which the gloves will provide protection and include data to demonstrate that the chemotherapy or other specialty gloves are safe and effective for handling the chemotherapy agents or other claimed special use. The applicant should include in the 510(k) submission:

- the product labeling which specifies the chemical that the glove provide protection against;
- the results of a controlled scientific study to substantiate the claim,
- the comprehensive description of the test method used,
- complete test protocol,

- an analysis of test results,
- discussion as appropriate, and
- conclusions.

To market the glove for use in the handling and/or preparation of chemotherapeutic drugs, the glove should be labeled as an "Examination Glove" and "Tested for use with [name of chemotherapeutic drug(s)].

Recommendations of additional information that should be provided or included in labeling are as follows:

- chemical resistance data (test method used, chemicals tested), to the consumer for review, if desired.

- the statement, “Gloves used for protection against chemotherapy drugs exposure must be selected specifically for the type of chemicals used.”

- Instructions to users to review material safety data sheets for the chemicals being used to determine the required level of protection.

The above statements/instructions would provide the user with the information needed to make an appropriate product selection.

The minimum biocompatibility tests for chemotherapy gloves are skin irritation and dermal sensitization.

**Non-Pyrogenic**

FDA does not believe that there is a medical basis for a non-pyrogenic claim for medical gloves, including surgeon's gloves.

**Hypoallergenicity**

FDA has received reports of sensitivity to medical gloves labeled as “hypoallergenic.” The latex labeling rule, published in the FR on September 30, l997, announced that effective September 30, l998, FDA will not allow the term “hypoallergenic” on the labeling of a natural rubber latex device. FDA believes that this term erroneously implies that the user of products labeled as hypoallergenic is assured that the risk of an allergic reaction to the chemicals or latex proteins in the products would be minimal. In the past, use of the “hypoallergenic” claim has been based on results of the modified (human) Draize test. While this test may be appropriate for detecting sensitivity to residual levels of processing chemicals, the test cannot accurately detect the presence or absence of natural latex proteins. Furthermore, current manufacturing processes cannot reduce the natural latex proteins below the level to which some individuals may be sensitive. Therefore, the FDA believes that the presence of the term “hypoallergenic” on the labeling of a natural rubber latex-containing device is misleading because it incorrectly implies that the product labeled as “hypoallergenic” may be used safely by latex sensitive persons.

**Special Label Claims**

The health care community and FDA are interested in improvements in the safety and performance of medical gloves. Some needed improvements are better barrier protection; better resistance to cuts, punctures and tears; longer shelf life and better biocompatibility characteristics. Some of these factors, such as biocompatibility, are addressed by CDRH guidance on protein claims, sensitization tests, irritation tests, etc.

If you wish to make claims not covered by FDA guidance or consensus standards, you should do the following in the order presented below:

- Discuss your proposed claims with the glove specialists in DSMA (phone 800-638-2041 in the U.S. or 301-443-6597), or

- Send a **letter** with a description of your product, your desired claims and preliminary data supporting the claims to:

  FDA Center for Devices and Radiological Health
  Infection Control Devices Branch, HFZ-480
  9200 Corporate Blvd.
  Rockville, MD 20850 USA

  Do **not** send a FAX or email.

- Mark each page of your letter confidential.

- Please describe any existing standards that your product meets or that may be used, or modified and used, to evaluate specific parameters of your product.

- The Office of Device Evaluation (ODE) will review your data and advise you on further tests and/or data requirements. If appropriate, you will be advised to meet with ODE representatives.

**LABEL EXHIBITS** - The following examples are consistent with proposed 21 CFR 801.440:

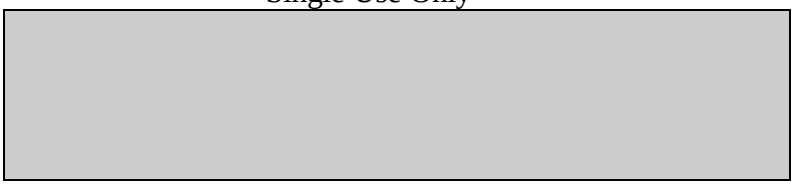
Example: **POWDERED** LATEX PATIENT EXAMINATION GLOVE BOX, TOP

**DR# GON® BRAND**
**POWDERED LATEX EXAMINATION GLOVES**

Powdered with absorbable dusting powder, U.S.P.

**Caution: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain no more than 120 mg powder and 1200µg extractable protein per glove. This product contains no more than 120 mg powder and 900µg extractable protein per glove.**

Single Use Only



**CONTENTS: 100 Gloves (by weight)**
**SIZE: MEDIUM**
**Distributed by:**
**ABC Corporation**
**Boston, MA 10001**

Example: **POWDERED** LATEX PATIENT EXAMINATION GLOVE BOX, SIDE

**DR# GON® BRAND**
**POWDERED LATEX EXAMINATION GLOVES**

CONTENTS: 100 Gloves (by weight) SIZE: MEDIUM
Powdered with absorbable dusting powder, U.S.P.

Singe Use Only

"**Caution**: Users should consider the circumstances of use in deciding whether to remove residual powder from gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method."

Distributed by:
ABC Corporation Expires: Aug. 2002
Boston, MA 10001 Product of Malaysia Lot: 020999

Sample: **POWDER-FREE** LATEX PATIENT EXAMINATION GLOVE BOX

# DR# GON® BRAND
# POWDER-FREE LATEX EXAMINATION GLOVES

**Lubricated with Silicone**

**Single Use Only**

**Caution: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain no more than 1200µg extractable protein per glove. This product contains no more than 300µg extractable protein per glove.**

**CONTENTS: 100 Gloves (by weight)**
**SIZE: MEDIUM**

**Manufactured For:**
**Andywill Care Inc.**
**Comfort, NC 27777 USA**

Sample: **POWDER-FREE** PATIENT EXAMINATION GLOVE BOX, SIDE

# DR# GON® BRAND
# POWDER-FREE LATEX EXAMINATION GLOVES

**Lubricated with Silicone**
**Single Use Only**
CONTENTS: 100 Gloves (by weight)
SIZE: MEDIUM

Manufactured For:
Andywill Care Inc. Expires: Dec. 2002
Comfort, NC 27777 USA Product of Thailand Lot: 051199

Sample: **POWDERED VINYL** PATIENT EXAMINATION GLOVE BOX

# DR# GON® BRAND
# POWDERED VINYL EXAMINATION GLOVES

**Powdered with absorbable dusting powder, U.S.P.**
**Single Use Only**

**Caution: Glove powder is associated with adverse reactions. FDA recommends that this product contain no more than 120 mg powder per glove. This product contains no more than 100 mg powder per glove.**

**CONTENTS: 100 Gloves (by weight)**
**SIZE: MEDIUM**

**Manufactured For:**
**Medical Art, Inc.**
**Terrell, MD 28888 USA**

Sample: **POWDERED VINYL** PATIENT EXAMINATION GLOVE BOX, SIDE

# DR# GON® BRAND
# POWDERED VINYL EXAMINATION GLOVES

CONTENTS: 100 Gloves (by weight) SIZE: MEDIUM

Single Use Only
Powdered with absorbable dusting powder, U.S.P.

"**Caution**: Users should consider the circumstances of use in deciding whether to remove residual powder from gloves after donning. Powder can be removed by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method."

Manufactured For:
Medical Art, Inc. Expires: Dec. 2002
Terrell, MD 28888 USA Product of Taiwan Lot: 031100

SAMPLE: **POWDERED** SURGICAL GLOVE UNIT PACKAGE

**↓↓ PEEL DOWN TO OPEN ↓↓**

# DR# GON® BRAND

# STERILE

# POWDERED LATEX SURGICAL GLOVES

**Single Use Only**

**Caution: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain no more than 120 mg powder and 1200 μg extractable protein per glove. This product contains no more than 120 mg powder and 300 μg extractable protein per glove.**

**CONTENTS: One Pair (2 Gloves)**

**SIZE: 7**

**Powdered with absorbable dusting powder**

CAUTION: After donning, remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method.

Lot: S101000 Expiration Date: Nov. 2002

Distributed by:
ABC Corporation
Big Apple, NY 10018 Product of Indonesia